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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/761,387

01/22/2004

Dennis M. Vigil

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EXAMINER

BOUCHELLE, LAURA A

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

05/22/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/761,387	<b>Applicant(s)</b> VIGIL ET AL.	
	<b>Examiner</b> LAURA A. BOUCHELLE	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5,9,10,12-14,17 and 19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5,9,10,12-14,17 and 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments filed 2/25/09 have been fully considered but they are not persuasive.
2. Applicant argues that Vigil has common inventors as well as common ownership with the instant application and that the Applicant had subsequently discovered an improvement to the device disclosed in the Vigil patent which the instant application is a result of. The examiner does not believe that this argument is an attempt to disqualify the Vigil patent under 103(c).
3. Applicant argues that the Edwards reference is unrelated to both the Vigil procedure and the instant application. The examiner disagrees. The basic teaching of Edwards which is relied upon currently is that when treating a body lumen by inserting needles into the tissue of the lumen it is desirable to minimize the damage that is done to the tissue. An even more basic teaching is that when a tissue is being treated it is desirable that the damage done to the tissue by the treatment is minimized. When looking for a method of releasing fluid into a vessel wall, one of skill in the art would look to similar methods for releasing fluid into any body lumen because the teachings on one would apply to another, especially the teachings regarding the structure of the device used to perform the method. So, given the similar subject matter – body lumens – and the motivation to not do damage to the very tissue that is being treated, the examiner believes that the combination is proper.

***Claim Rejections - 35 USC § 103***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1, 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vigil et al (US 5746716) in view of Edwards (US 6009877). Vigil discloses a method of releasing fluid medicament into a vessel wall comprising the steps of providing an expanding member 16 having a plurality of dispensers 20, advancing the expanding member through the vessel to the site, moving the expanding member from a first configuration to a second configuration, and releasing fluid medicament through the dispensers into the vessel wall (Col. 3, lines 50-65, Col. 5, lines 17-30).
3. Claims 1, 10 differ from Vigil in calling for the dispensers to be provided in a single plane only. Edwards teaches a method for treating a body lumen including an expandable member 44 having dispensers 90 mounted on the expandable member. The method of using the device as taught by Edwards is similar to that of Vigil. Edwards teaches that the dispensers 90 are located in a single plane (see Fig. 14) to allow for treatment of a limited and precise area of the lumen while minimizing trauma to the lumen and the surrounding area (Col. 3, lines 36-39). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Vigil to include dispensers in a single plane only as taught by Edwards to minimize injury to the body lumen.
4. Claims 2, 3, 12, 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vigil in view of Edwards in view of Rammler (WO 94/23787). Claims 2, 12, 21 differ from Vigil in

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calling for the fluid medicament to inhibit the proliferation of smooth tissue growth. Claims 3, 13, 22 differ in calling for the fluid medicament to include a radioactive isotope. Rammler teaches a balloon catheter for delivery of drugs to a site in a vessel comprising the step of delivering a cell proliferation inhibitor to prevent restenosis of the region (Page 6, line 35). Rammler also teaches that the balloon catheter may be used to deliver a radioactive isotope to provide for better definition of the vessel wall under fluoroscopy (Page 8, line 31). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Vigil to include the steps of delivering a cell proliferation inhibitor or a radioactive isotope as taught by Rammler to treat a vessel wall.

5. Claims 4, 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vigil in view of Edwards in view of Goldberg et al (UUS 5480975). Claims 4, 14, 23 differ from Vigil in calling for the fluid medicament to stimulate production of collateral vessels. Goldberg teaches the use of a medicament that stimulates the production of collateral vessels to ameliorate hypoxic injury (Col. 2, lines 53-58). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Vigil to include the steps of delivering a medicament that stimulates the production of collateral vessels as taught by Goldberg to ameliorate hypoxic injury to tissues.

6. Claims 7, 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vigil in view of Edwards in view of Casscells et al (WO 9211872). Claims 7, 17, 26 differ from Vigil in calling for the fluid medicament to comprise a binder. Casscells teaches the use of a binder that binds to the vessel wall so that drug agents can enter the target cells and destroy proliferating cells (see abstract). Therefore, it would have been obvious to one of ordinary skill in the art at

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the time of invention to modify the method of Vigil to include the steps of delivering a binder as taught by Casscells to allow drug agents to enter the target cells and destroy proliferating cells.

7. Claims 9, 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vigil in view of Edwards in view of Nabel et al (US 5328470). Claims 9, 19, 28 differ from Vigil in calling for the medicament to comprise a gene for gene therapy. Nabel teaches the use of medicaments comprising a gene for gene therapy to a localized region of vessel injury (Col. 5, lines 60-65). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Vigil to include the step of providing a medicament having a gene for gene therapy as taught by Nabel to treat a localized region of vessel injury.

### ***Conclusion***

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA A. BOUCHELLE whose telephone number is (571)272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura A Bouchelle  
Examiner  
Art Unit 3763

/Laura A Bouchelle/  
Examiner, Art Unit 3763

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763